

**REMARKS**

**I. Status and Disposition of the Claims**

Applicants acknowledge, with appreciation, the Examiner's withdrawal of the finality of the Final Office Action of November 1, 2006 pursuant to 37 CFR 1.114 and the entry of the submission filed on September 28, 2007. Consequently, claims 7 and 20-26 are currently pending.

The Examiner continues to reject claims 7 and 20-26 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 6,325,766 ("Anderson") in view of U.S. Patent No. 5,722,981 ("Stevens"). See Office Action at 2-3. The Examiner also rejects claims 7 and 22-26 over "Yamauchi et al. ('159)"<sup>1</sup> in view of U.S. Patent No. 6,428,317 ("Abel"). *Id.* at 3-4. Applicants respectfully disagree with and traverse each of these rejections for at least the following reasons.

**II. Response to Rejections**

**A. The §103(a) rejection of claims 7 and 20-26 in view of Anderson and Stevens is improper.**

The Examiner has rejected claims 7 and 20-26 under §103(a) as allegedly unpatentable over Anderson in view of Stevens. Office Action, pages 2-3. According to the Examiner, Anderson discloses the limitations in claims 7 and 22-26, including:

1. an elongated medical device having a superelastic member (12) having a first set of properties; and
2. an adjacent second section (14) having a second set of properties. *Id.* at 2.

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<sup>1</sup> The Examiner did not provide a complete citation of the "Yamauchi et al. ('159)" reference. Based on references of record, Applicants assume Yamauchi et al. to refer to Japanese Patent Application Publication No. JP 04 187159. Clarification is requested.

The Examiner acknowledges that although Anderson discloses using any pseudo- or super-elastic alloys or shape memory nickel-titanium alloys for the second section, it "fails to disclose the alloy including an easily diffusible element consisting of oxygen or hydrogen." *Id.* at 2. However, the Examiner alleges: "Stevens teaches a nickel-titanium alloy having a reduced superelasticity which include oxygen or hydrogen." *Id.* at 2. Consequently, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to "substitute one alloy for the other to achieve the predictable results of allowing the medical device to have a pre-formed shape, be stressed into another shape, and then return to its pre-formed shape" Office Action, pages 3. Applicants respectfully disagree.

To establish a prima facie case of obviousness, three basic criteria must be met. These criteria include that the Examiner show there would have been some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify and combine reference teachings, and that the Examiner show that there would have been a reasonable expectation that the proposed modification will be successful. See M.P.E.P. 2143.02. If no such reasonable expectation of success exists, the proposed modification could not have been obvious. *Id.* Furthermore, the proposed modification cannot be considered obvious if it would render the prior art unsuitable for its disclosed purpose. See M.P.E.P. 2143.01. Applicants respectfully point out that neither requirement can be met for the combination and modification proposed by the Examiner.

First, neither Anderson nor Stevens discloses treating a superelastic member in an elongated device with an easily diffusible element selected from oxygen, nitrogen, and hydrogen, as claimed. As the Examiner acknowledges, Anderson does not disclose the alloy including an easily diffusible element consisting of oxygen or hydrogen." Office Action at 2. If fact, the alloy used to construct the device could be either superelastic NiTi containing carbon, or stainless steel, or "cobalt based MP35N and L605, and Elgiloy." Anderson, column 2, lines 13-18, and 38-62. To the extent that Anderson teaches anything related to hydrogen, oxygen, or nitrogen, it merely is to show that such elements can exists in small amounts in alloys. Anderson does not disclose treating any alloy with hydrogen, oxygen, or nitrogen, and certainly not to affect the alloy's properties.

Stevens is even more deficient in that it does not mention hydrogen, oxygen, or nitrogen. Rather, this reference described using commercially available alloys. See Stevens, col. 3, lines 42-49, teaching that its preferred material is available from Shape Memory Applications, Inc. of Sunnyvale, Calif. Thus, Stevens clearly does not remedy the deficiencies of Anderson.

Second, none of the cited references teaches treating a specific section of the medical device to change the properties of that particular section. Although Stevens discloses a NiTi alloy having other elements, Stevens does not correct Anderson's failure to teach an elongated member having two adjacent superelastic sections, much less two adjacent superelastic portions wherein one portion exhibits altered properties as a result of being treated with an easily diffusible element selected from oxygen, nitrogen, and hydrogen, as claimed. Thus, even if, *arguendo*, one of ordinary skill in the

art would have been motivated to combine Anderson with Stevens in the manner suggested by the Examiner, the resulting combination would still fail to teach or suggest each and every element of at least claim 7.

Therefore, Anderson and Stevens, individually or in combination, do not teach a medical device having two sections made with alloys of different properties. They certainly do not provide a motivation or suggestion to treat a section of a medical device of the claimed invention to alter its properties. Since treating a section of a medical device with a diffusible element was never mentioned in the references, one of ordinary skill in the art at the time of invention would not have thought of such an unique way of obtaining a medical device, much less having an expectation of the success. The Federal Circuit has repeatedly warned that the requisite motivation must come from the prior art, not applicant's specification. *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531-1532 (Fed. Cir. 1988) ("[t]here must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure."). Using an applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravenes the statutory mandate of section 103 of judging obviousness at the point in time when the invention was made. See *Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

In view of the complete lack of teaching or suggestion in the cited references, alone or in combination, one can objectively conclude that the Examiner has improperly reconstructed the claimed invention by using Applicants' disclosure. Applicants, therefore, respectfully request withdrawal of the rejection based on the above reference.

**B. The §103(a) rejection of claims 7, 10, and 22-26 in view of Yamauchi in view of Abel is improper.**

The Examiner next rejects claims 7, 10, and 22-26 under 35 U.S.C. § 103(a) as unpatentable over Yamauchi in view of Abel. Office Action at 3. Since claim 10 has been previously cancelled, the rejection to claim 10 is moot. With respect to the rejection to claims 7 and 22-26, Applicants disagree for at least the following reasons.

The Examiner alleges that Yamauchi discloses claimed limitations except for “the easily diffusible element being selected from the group consisting of oxygen, hydrogen and nitrogen.” *Id.* Abel, the Examiner maintains, “teaches that heat treatments and/or the addition of elements such as oxygen (O) and nitrogen (N) to nickel-titanium alloys can be very significant effects on desired superelastic properties and performance of the material.” *Id.* at 3. Abel does not teach diffusing hydrogen, oxygen, or nitrogen into a nitinol alloy after the alloy has been formed. Rather, it merely describes alloys comprising trace amounts of such elements that result from their fabrication, not treating such alloys after they are produced. Thus, Anderson does not disclose treating any alloy with hydrogen, oxygen, or nitrogen, and certainly not to affect the alloy’s properties.

Applicants submit that, similar to the reasons of record, Abel does not teach treating a section of an alloy medical device to alter its properties, as claimed. One of ordinary skill in the art, knowing that treating the alloy with oxygen or nitrogen alters the properties of the alloy by reading Abel, still can not arrive at the specific medical device as claimed.

Furthermore, Abel is vague on what "significant effects" on what "desired superelastic properties and performance of the materials." See Abel at 10-14. Hence there is no indication, either in Yamauchi or in Abel, as to why NiTi treated with oxygen and/or hydrogen would be beneficially used in Yamauchi's device.

For at least the foregoing reasons, Applicants submit that the Examiner has not established a prima facie case of obviousness in rejecting the claimed invention. Applicants respectfully request the rejections withdrawn.

### **III. Conclusion**

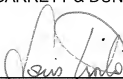
In view of the foregoing remarks, Applicants submit that the claimed invention is not rendered obvious in view of the prior art references cited against this application. Applicants therefore request reconsideration of the application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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By:   
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